General Guidance on e-Consent in REDCap

The instructions below are meant as a general guide, but please schedule an appointment with a REDCap administrator to go through the details of setting up e-consent. We advise speaking to the REDCap team before submitting to the IRB if possible. If not possible, you'll want to meet with the REDCap team before going live with your project.

Specifics may differ for your project based on your team's goals and what the IRB has approved. Keep in mind that what's most important is proper documentation of your consent process and a clear trail of adherence to your specific approved process.

At CHOP, electronic consent (e-consent) can be used for a variety of research protocols. The IRB can tell your research team if e-consent can work for your protocol. If your research requires FDA oversight, REDCap may not be sufficient for Part 11 Compliance. Check with ORC/IRB.

Once the IRB has approved your study's use of e-consent, you can get started on your consent form in REDCap. Your consent form doesn't have to be finalized to start creating your REDCap form, but it should be in IRB review.

You also may need to get permission from the IRB at this point to collect identifiers on the consent form, particularly

1. Email address (to automatically send copy of consent form)
2. Date of birth (to calculate age)

**Steps for Creating Your Consent Form(s)**

1. You'll **create a form** in your REDCap project for each consent form you need for that project.

   There are **two options** for getting the text of your paper consent form into REDCap:

   1. Take the text directly from your approved consent and **copy-paste** into Descriptive Text fields within your Informed Consent form. You can use one long Descriptive Text field, or split the text up into several fields. You may want to use section breaks and HTML to manipulate your text in this process.

General Guidance on e-Consent in REDCap

2. Take **screenshots** of the individual pages of your consent form and upload individually into Descriptive Text fields in your form, displaying each as Inline images:
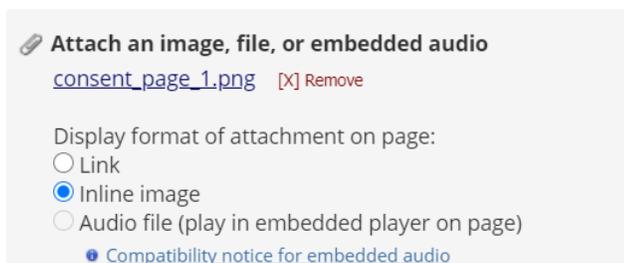
There are positives and negatives to both approaches, and you'll need to choose what works best for your study:

	Pros	Cons
Copy/paste text method	• Works well across devices • Eliminates redundant fields	• Copying/pasting/HTML can lead to human error
Screenshot method	• Exact copy of paper consent – no possibility of copy/paste error • Already formatted, doesn't need additional formatting in REDCap	• Need to include signature page images, but also need to re-create signature fields in REDCap – can look redundant • Need to test thoroughly on phones and tablets to make sure screenshots are readable

2. Use **signature fields** within your project to obtain subject signatures. Make sure you include signature fields for everyone from whom you may need to obtain a signature – parent consenting for self, parent consenting for child, child consenting if over 18, etc. It's recommended to make these fields **required**.
3. Include **date fields** along with signature fields so participants can choose "today" at the time of signature.
4. Include **text fields** for first and last name.
5. Include any other fields you have on your paper consent form.

General Guidance on e-Consent in REDCap

6. As participants will be filling this out themselves, you'll need to **enable surveys overall for your project**, then enable the Consent form as a survey. To enable surveys overall for the project (if you haven't already), navigate to the "Project Setup" tab and click "Enable" next to "Use surveys in this project". If your project is already in Production mode, you'll need to contact a REDCap administrator to turn this feature on for you:

Then **enable your Informed Consent Form as a survey** within the Online Designer:

Refer to the Enable Surveys document on the REDCap Intranet page for more guidance if needed.

7. Once you have enabled your Informed Consent form as a survey, **enable the e-Consent framework** on the Survey Settings page:

General Guidance on e-Consent in REDCap

8. Set your project up to email a copy of survey to participant – also set at the bottom of the survey settings. This automated email ensures that Consent forms always include PHI, so you **must** use [SEND SECURE] in your subject line for security:

You'll need to use the Designated Email Field setting to make this automated email work. See our Participant List guidance document for more information.

9. When your e-consent is set up, the IRB may want to see a PDF of the completed consent form in REDCap. You can download a blank PDF of the form from the Online Designer:

If there's extensive branching logic, the IRB may want you to provide different versions depicting the different consent scenarios. If that's the case, you can enter a consent using test data to show the branching logic, then download the PDF from within that record.

If you used screenshots of your consent form, you'll need to **replace the screenshots you used with the final IRB stamped and approved version** of each page before using the consent form.

Once enabled, the e-consent framework provides:
- An end-of-survey certification notifying the participant that signing the e-consent form is the equivalent of signing a paper document:

  ☐ I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

- Auto-archival of the signed PDF in the project's File Repository
- Space to include the e-consent version and the participant's first and last name on the PDF

General Guidance on e-Consent in REDCap

Additional considerations
Staff Signatures
- E-consent can be used for both in-person and remote consenting. Will staff sign the consent in person with subject? Or after subject has submitted the consent remotely?
  - This will determine whether you'll check the "Allow e-consent responses to be edited by users" box.
  - This may also affect decisions like whether to hide the staff signature fields from the survey using the **@HIDDEN-SURVEY** action tag (useful if staff will sign after subject submits survey).

Version Control
- Will you be consenting over a long period of time and therefore changing the consent with new language and fields?
  - If yes, consider using **additional version control** besides the version option within the eConsent framework. There are two options for this:
    - **Separate instruments:** Create a new instrument for each new consent form. This is an easy option if there will only be a couple updates- you'll "retire" old consents by taking the survey offline and moving the instrument to the bottom of your list of instruments (in Online Designer).
    - **Single consent with branching logic:** If you will have many consent versions, you might want to keep a single consent form and use branching logic to show/hide changes to any language. To do this, you must use a hidden "Version" multiple choice field that is defaulted to the current version. Descriptive text fields with new or changed language can use branching logic to be hidden/shown based on the version. Any new version number must be added to the multiple choice list, and the @DEFAULT action tag must be updated accordingly.

Required Fields
- You may also want to **mark fields required** so that participants cannot leave important fields blank – this can apply to lots of fields within your consent, but especially **name, date, and signature fields.**

Branching Logic
- You can use branching logic to set up your consent form so that participants only see the fields they need to fill out.